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THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			COE, SUSAN D	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 20040519

Application Number: 09/609,622
Filing Date: July 05, 2000
Appellant(s): SUNVOLD ET AL.

Kelly L. McDow-Dunham
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 24, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 15-18 and 24 do not stand of fall together with claims 19-23 and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

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5,240,962

NAKATSU et al.

8-1993

Purina CNM Veterinary Product Guide (published in 1994 by the Ralston Purina Company), pp. 16 and 17.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 15-24 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,626,849, the Purina CNM Veterinary Product Guide (published in 1994 by the Ralston Purina Company, pp. 16 and 17), and US Pat. No. 5,240,962.

Appellant's claims are drawn to a composition comprising l-carnitine, chromium, Vitamin A, and a carbohydrate selected from sorghum, barley, or a mixture thereof. The composition is formulated as a solid pet food and is intended to induce weight loss.

The Purina Product Guide teaches a food for obese dogs that causes weight loss by restricting calories and fat while being high in dietary fiber. The dry food contains 21.17% protein, 5.6% fat, and 14.14% fiber. The ingredients of the dry food include ground corn and vitamin A (see pages 16 and 17). The reference does not teach using sorghum, barley, l-carnitine, or chromium in the composition.

US '962 teaches a food for reducing weight in animals. The reference teaches using corn, sorghum, or barley as the carbohydrate source for the weight reducing food. Thus, the reference shows it was known in the art at the time of the invention that corn, sorghum, and barley can be used interchangeably as the carbohydrate source in a weight loss food. Therefore, a person of ordinary skill in the art would reasonably expect that substituting sorghum and / or barley for the corn in the Purina weight loss food would be successful. Based on this reasonable

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expectation of success, a person of ordinary skill in the art would be motivated to make this substitution.

Thus, US '962 and the Purina Product Guide together are considered to teach a solid pet food for weight reduction that comprises Vitamin A, sorghum, and / or barley. These references do not teach adding chromium and L-carnitine to the food. However, US '849 teaches that both of these ingredients are well known in the art for inducing weight loss. Thus, a person of ordinary skill in the art would reasonably expect that these weight loss inducing agents would be beneficial additions to the weight loss food taught by US '962 and the Purina Product Guide. Based on this reasonable expectation of beneficial results, an artisan of ordinary skill would have been motivated to combine chromium and L-carnitine with the food containing Vitamin A, sorghum, and / or barley.

These references together teach a composition comprising chromium, L-carnitine, vitamin A, sorghum, and barley; however, they do not specifically disclose adding the ingredients in the specific amounts claimed. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve weight loss. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

(11) *Response to Argument*

Regarding the 103(a) rejection over US Pat. No. 5,626,849, the Purina CNM Veterinary Product Guide (published in 1994 by the Ralston Purina Company, pp. 16 and 17), and US Pat. No. 5,240,962, the appellant argues that US '849 does not teach or suggest pet foods or a composition comprising vitamin A, sorghum, or barley. The appellant also argues that the Purina Product Guide does not teach a diet that contains chromium, L-carnitine, sorghum, or barley. In addition, the appellant argues that US '962 teaches using phenols to control weight and only states that sorghum and barley can be used as carbohydrate sources, not as active ingredients. The appellant also states that US '962 does not teach using chromium, L-carnitine, and vitamin A. The appellant argues that the references taken together do not teach or provide proper motivation for combining their disclosures together. The appellant argues that Purina teaches using corn in each and every diet; thus, one of ordinary skill in the art would not be motivated to select corn for use in weight management. The appellant also argues that a person of ordinary skill in the art would not equate sorghum or barley with corn in the diets of Purina and would not be motivated to interchange them.

However, these arguments are not found persuasive for the following reasons. The rejection is based on a specific Purina pet food described on pages 16 and 17 of that reference. No other pet food taught by that reference is now or ever has been included as a basis of the rejection. This specific pet food, the OM-formula, is specifically designed for treating obesity. In addition to other ingredients, the composition contains corn and Vitamin A. Corn is the first listed ingredient; thus, it is obviously the largest carbohydrate source used in the pet food. Thus, the weight loss food needs a carbohydrate source. US '962 teaches another animal food that has

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differing active ingredients for inducing weight loss and reducing fat in animals. In addition to the active ingredient, this reference also teaches that the food needs to contain a carbohydrate source to provide complete nutrition for the animal. These carbohydrate sources are selected from corn, sorghum, or barley (see column 5, lines 31-35). Thus, US '962 teaches that sorghum and barley are functionally equivalent to corn when used as a carbohydrate source in an animal food. Therefore, a person of ordinary skill in the art would reasonably expect that sorghum and barley can successfully be used in place of the corn taught by Purina. Thus, the combination of US '962 and Purina would yield a pet food with sorghum and / or barley as the carbohydrate source with Vitamin A also in the composition. This rejection is not intended to be a "selection" of corn as stated by appellant, but as an obvious modification of the Purina OM-formula to substitute corn with barley and / or sorghum. In summary, the combination of the Purina reference and US '962 yields a modified Purina OM-formula that contains sorghum and / or barley in place of the corn. These references do not teach adding chromium or L-carnitine to the composition. However, US '849 teaches that chromium and L-carnitine can be used to induce weight loss in any mammal. Thus, a person of ordinary skill in the art would reasonably expect that these weight loss inducing agents would be beneficial additions to the weight loss food taught by US '962 and the Purina Product Guide. Based on this reasonable expectation of beneficial results, an artisan of ordinary skill would have been motivated to combine chromium and L-carnitine with the food containing Vitamin A, sorghum, and / or barley.

The appellant also argues that the prior art references do not teach using the ingredients in the amounts claimed by the appellant. However, in regards to chromium, US '849 does teach using amounts that fall within the appellant's claimed ranges. The reference specifically states

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that the composition can contain 50 micrograms of chromium (see column 1, lines 60 and 61).

The appellant argues that the amounts claimed are much lower than taught for L-carnitine.

However, a person of ordinary skill in the art would be motivated to modify a parameter such as ingredient amount to determine the lowest dosage that would produce the desired results.

Optimizing for the lowest dosage is obvious to do in regards to both a financial and medical standpoint. From a financial standpoint it is desirable to use the smallest effective amount of an ingredient because it would reduce the cost of making the composition. From a medical standpoint it is desirable to use the smallest effective amount because it reduces the chance of toxicity and adverse interactions with other drugs. Thus, it is considered obvious to optimize the amount of each ingredient to best achieve the effects of the invention in regards to all aspects of drug development. The appellant also argues that none of the references teach what amount of Vitamin A to use. However, the amount of Vitamin A claimed is a known pharmaceutically acceptable amount. In addition, the optimization of Vitamin A is considered an obvious modification for the reasons discussed.

The appellant also argues that the claimed diet has unexpected results based on the comparisons between Diet A (Hill's Prescription Diet w/d Canine) and Diet B (Eukanuba Veterinary Diets Nutritional Weight Maintenance Formula Glucose-Control Canine) which is supplemented with chromium sorghum and barley. Appellant has provided a list of the ingredients of each diet. Firstly, these diets contain numerous ingredients that are not included as ingredients in appellant's claimed pet food. Secondly, the data do not clearly support a claim of unexpected results because Diet A and Diet B each contain very different ingredients. Thus, the two diets are not directly comparable. Because of the different ingredients, it cannot be

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determined if Diet B functions better than Diet A because of the supplementation with the chromium and L-carnitine or because of some ingredient in Diet B that is not an ingredient in the appellant's claimed diet. Therefore, any potential unexpected results are not clear and are not commiserate in scope with appellant's claims.


For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




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Examiner
May 19, 2004

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